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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/924,099	08/08/2001	Yoshihiro Nishida	NISHIDA=3A	3370

7590 04/07/2004

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EXAMINER	
JIANG, DONG	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 04/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/924,099	NISHIDA ET AL.	
	Examiner	Art Unit	
	Dong Jiang	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *47-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *47-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/338,511

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED OFFICE ACTION

The request filed on 18 February 2004 for a Continued Examination (RCE) under 37 CFR 1.114 based on parent Application No. 09/924,099 is acceptable, and a RCE has been established. An action on the RCE follows.

Applicant's amendment filed on 18 February 2004 is acknowledged and entered. Following the amendment, claims 47-50 are amended, and the new claims 51-54 are added.

Currently, claims 47-54 are pending and under consideration.

Withdrawal of Objections and Rejections:

The rejection of claims 47-50 under 35 U.S.C. 103(a) as being unpatentable over Taniguchi et al. (J Immunol. Methods, 1997, 206: 107-113), in view of Kohno et al. (Clin. Immunol. Immunopath., January 1998, 86(1): 11-15), and Huston et al. (Proc. Natl. Acad. Sci., 1988, 85(16):5879-83) is withdrawn in view of applicant's amendment.

Formal Matters:

Claim 51 is objected to for the following informalities, appropriate correction is required for each item:

The term "living dofy" in line 2 should be "living body".

Objections and Rejections under 35 U.S.C. 112:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 47-50 remain rejected, and the new claims 51-54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 47 remains indefinite for the recitation of "comprises *constant regions*" in line 9. As the claim merely indicates that said constant regions being not equal to the sequence of the constant region of said IL-18 antibody, and does not positively recited what the constant regions are, it is unclear that it is "constant regions" of what. Claims 48-50 are similarly indefinite.

The remaining claims are rejected for depending from an indefinite claim.

Rejections Over Prior Art:

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 47-50 remain rejected, and the new claims 51-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taniguchi et al. (J Immunol. Methods, 1997, 206: 107-113), in view of Kohno et al. (Clin. Immunol. Immunopath., January 1998, 86(1): 11-15), and Riechmann et al. (Nature, 1988, 332:323-327), for the reasons of record set forth in the last Office Action, paper No. 12, mailed on 27 August 2003, at pages 3-4.

Applicants argument filed on 18 February 2004 has been fully considered, but is not deemed persuasive for reasons below.

At pages 8-9 of the response, the applicant argues that Taniguchi does not teach an artificially produced peptide in which the constant regions are not equal to the constant regions

of non-human anti-IL-18 antibodies, nor Taniguchi teaches or suggest the use of the antibody for the treatment of rheumatoid arthritis, that Kohno teaches nothing about the artificially produced peptide of the present invention, and its use for treatment, and that thus, a person of ordinary skill in the art would not have been motivated to modify the IL-18 antibody to obtain artificially produced peptide for neutralizing IL-18 following Riechmann's teachings. This argument is not persuasive because applicant's argument is against the references *individually*, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In the instant case, even though none of the references teaches an artificially produced peptide capable of neutralizing IL-18, and its use in the treatment, suggestion or motivation to do so can be found based on *combination* of references, which teach a mouse anit-human IL-18 monoclonal antibody capable of neutralizing IL-18 (by Taniguchi), a pathological role of IL-18 in diseases such as RA and methods of administering anti-IL-18 antibodies for treating a pathological condition (by Kohno), and a method of making a humanized antibody minimizing the anti-globulin response during therapy (by Riechmann). Therefore, it is logical and obvious to a skilled artisan to antagonize the action of IL-18 in treating RA by using an artificially produced peptide capable of neutralizing IL-18, such as a humanized antibody. A person of ordinary skill in the art would have been motivated to do so for disease treatment in humans, and for minimizing the potential side effect of the non-human antibody based on the teachings of the three references.

With respect to the dosage limitation in the new claims 51-54, given the state of the art at the time the present invention was filed, a person skilled in the art will readily be able to determine the effective amount of the active ingredient. Further, given the fact that "a dose of

1 ug to 1 g" in the present claims represents a very broad dose range (10^6 magnitude), an artisan would have to determine a specific therapeutically effective amount suitable for each specific condition within the scope of sound medical judgment, as the dose level will depend upon a variety of factors.

Conclusion:

No claim is allowed.

Advisory Information:

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Lorraine Spector

LORRAINE SPECTOR
PRIMARY EXAMINER

Dong Jiang, Ph.D.
Patent Examiner
AU1646
4/1/04